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PATENT
671302-2008REMARKS

The Office Action of June 16, 2006 requires an election under 35 U.S.C. § 121 from among the following:

- I. Claims 1-14, allegedly drawn to a method for preparing a basement membrane on support structure with a sugar-chain coat, classified in class 435, subclass 174.
- II. Claims 15-16, allegedly drawn to a kit containing a tissue model, classified in class 435, subclass 1.1 and 975.
- III. Claims 17-27, allegedly drawn to method for constructing a basement membrane specimen wherein cells are removed using a solvent having the ability to lyse lipid of the cells, classified in class 210, subclass 634.
- IV. Claims 28-29, allegedly drawn to a basement membrane specimen having no support structure, classified in class 435, subclass 41.
- V. Claims 30-40, allegedly drawn to a process for producing a reconstituted artificial tissue, classified in class 435, subclass 325.
- VI. Claims 41-44, allegedly drawn to artificial tissue, classified in class 623, subclass 23.72.
- VII. Claim 45, allegedly drawn to method for testing the safety and toxicity of a artificial substance, classified in class 424, subclass 9.1.
- VIII. Claims 46-57, allegedly drawn to an artificial tissue, classified in class 106, subclass 4.
- IX. Claims 58-67, allegedly drawn to a process for producing transplantable tissue, classified in class 623, subclass 1.38.

Group I, claims 1-14, is elected with traverse for further prosecution in this application. Applicants reserve the right to file divisional applications to non-elected subject matter.

As a traverse, it is noted that the MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct (MPEP § 803). Second, searching the additional inventions must constitute an undue burden on the Examiner if restriction is not required. *Id.* The MPEP directs the Examiner to search and examine an entire application "[i]f the search and examination of an entire application can be made without serious burden, ...even though it includes claims to distinct or independent inventions." *Id.*

It is respectfully submitted that the criteria listed in MPEP § 803 have not been met in this case, as no showing has been made that an undue burden would be placed on the Examiner. The

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present application relates to a method for preparing and constructing a basement membrane specimen, the basement membrane specimen itself, and a process for producing artificial tissue involving these methods. Accordingly, there is a relationship among the methods disclosed in the present invention.

The Office Action states that "each of the processes require different process steps and hence each are independent and distinct from each other." The Applicants respectfully disagree, as the claims of Groups I, III, V, VIII and IX are comprised of methods that overlap among the alleged groups. Indeed, any search for the methods of group I would certainly be co-extensive with the claims of groups III, V, VIII, and IX. For instance, the claims of Groups III, V, VIII, and IX all involve basement membranes and cells having an ability to form a basement membrane, thereby indicating that these methods are related. This is further supported by the classification of the groups, as Group I and Group V are categorized in class 435.

In addition, the same claim elements are presented in Groups I, III, V, VIII, and IX. For example, claim 1 of Group I, claim 25 of Group III, claim 38 of Group V, claim 51 of Group VIII, and claim 63 of Group IX all specify a method involving "culturing cells having an ability to form a basement membrane on a support structure with a sugar-chain coat which can localize a receptor having an activity to accumulate a basement component..." Furthermore, claim 17 of Group III, claim 32 of Group V, claim 49 of Group VIII, and claim 61 of Group IX all involve "removing the cells having an ability to form a basement membrane which are adhered onto a support structure through a basement membrane...using a solvent having the ability to lyse lipid of the cells and an alkaline solution." Therefore, it is respectfully submitted that it would not place an unnecessary burden on the Examiner to search and examine Groups I, III, V, VIII, and XI together, as a search for the methods of Group III would necessarily include Group I, and the search for the methods of Group V, VIII, and XI would necessarily include Groups I and III.

Enforcing the present restriction requirement and election of species would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since the requisite showing of serious burden has not been made in the Office Action and there are relationships between the claimed combinations. Indeed, the search and examination of at least

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groups I, III, V, VIII, and IX would involve such interrelated art that the search and examination of at least groups I, III, V, VIII, and IX can be made without undue burden on the Examiner. All of the preceding, therefore, mitigate against restriction.

In view of the above, reconsideration and withdrawal of the Requirement for Restriction and election of species are requested, and an early action on the merits earnestly solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

By: Deborah L. Lu
Thomas J. Kowalski
Reg. No. 32,147
Deborah L. Lu
Reg. No. 50,940
Tel (212) 588-0800